CTMS/CDUS SIG Teleconference
Meeting Minutes

Meeting Date	Wednesday, September 15, 2004 12-1 PM EDT
Attendees:	**Working group coordinators**: Scott Finley (Booz Allen Hamilton) Harshawardhan Bal (Booz Allen & Hamilton) **Participants:**

Name	Email	Center
Rhoda Arzoomanian (SIG lead)	rza@medicine.wisc.edu	Wisconsin
Brenda Crocker	crockerbl@msx.upmc.edu	UPMC
Connie Kiefer	ckiefer@ctisinc.com	CTIS
John Speakman	speakman@biost.mskcc.org	Sloan-Kettering
Joyce Niland	jniland@coh.org	City of Hope
Michael Becich	becich@pitt.edu	UPMC
Richard Evans	evans_r@ccnt.hsc.usc.edu	USC
Rick Magnan	magnan@jimmy.harvard.edu	Harvard university
Sharon Elcombe	elcombe@mayo.edu	Mayo
Sorena Nadaf	s.nadaf@vanderbilt.edu	Vanderbilt
William Price	wprice@theradex.com	CTMS

Agenda:	1. Review of Minutes of last Teleconference 2. Discussion of Data Transmission Standards 3. Discussion of CTMS/CDUS/AE Reporting Survey Updates 4. Future Plans 5. Plans for next Face to Face Meeting, November 16-17, 2004 6. Next Teleconference: September 22nd, 12-1 pm EDT
General discussion points raised by participants:	Connie Kiefer mentioned that a document regarding the implementation process of a CTEP initiated secure FTP project to enhance security and confidentiality when transferring files over the Internet was sent along with

a questionnaire on Friday 09/10/2004 to all FTP submitters (primary submitters and not secondary submitters) who submit data to the CDUS system. A number of attendees requested the document be sent to them. Connie Kiefer agreed to send a revised document to circulate to all CTMS/CDUS SIG participants.

Joyce Niland mentioned that responses for the latest AE CTMS/CDUS survey were starting to roll in and that the feedback from the responses would be added to the survey summary. Amy Cox to send the latest CTMS/CDUS reporting survey to Connie Kiefer and Bill Price.

The group continued the discussion on the subject of data capture elements for CTMS/CDUS reporting as an important milestone for caBIG and how the SIG could achieve the goal of harmonization where each center accepted a common code for all fields and apply a uniform set of rules in a standardized manner. Connie Kiefer mentioned an effort with the NCI to harmonize the terms in CDUS to be compliant with CDE standards and how this would fit with the goals of the SIG. Scott Finley suggested that it would be useful if the multiple reporting systems such as CTMS and CDUS used the same CDE standard terminology. Bill Price added that they were not planning changes to their case report forms in the near term although they were always compatible with CDUS, since changes in the definition of fields led to incompatibility issues with the large number of centers that they dealt with. Scott suggested supporting an additional reporting model instead of an entirely new form that would be incompatible with the earlier form.

The relationship between caBIG, CDE and caDSR and vocabularies was discussed with respect to aligning CTMS and CDUS with standard CDEs. Scott Finley suggested the involvement of the VCDE workspace (through the workspace lead Christine Richardson) in the CTMS/CDUS Reporting SIG as a way to approach this issue. Joyce Niland mentioned that Hemant Shah the COH vocabulary specialist was working on an SOW to provide a mapping facility that could be employed for aligning the CTMS and CDUS with CDEs.

John Speakman offered to obtain information from Beverly Meadows (CTEP) on the issue of how standardized the different reporting systems and NCI are in terms of CDEs and also find out if she was involved with the VCDE efforts. The group also felt that it would be useful to have Beverly Meadows participate in the teleconference and present her views and clarifications on these issues. The group agreed to Sharon Elcombe's suggestion of integrating the efforts of DCP who have their own set of CDEs and their own system for adverse events reporting, with this effort. Connie Kiefer explained that this would be important given that there are guidelines for CDUS that are DCP protocols and the fact their rules are different than CTEP because they deal with different types of studies. Joyce Niland added that Amy Cox from COH was creating an Adverse Events reporting work flow that outlined how DCP Adverse Events reporting differs in a attempt to harmonize the different requirements across the different types of trials.

Action items	- Send revised CTEP secure FTP implementation document and questionnaire to Harshawardhan Bal and Rhoda Arzoomanian (Connie Kiefer) - Send the latest CTMS/CDUS reporting survey to Connie Kiefer and Bill Price (Amy Cox) - Explore involvement of VCDE in the CTMS/CDUS Reporting SIG teleconferences. Obtain information from Rebecca Crowley who is part of the VCDE workspace and report to the group (Brenda Crocker). - Obtain information from Beverly Meadows (CTEP) on how standardized the different reporting systems and NCI are in terms of CDEs and also find out if she was involved with the VCDE efforts and if she could participate in the next CTMS/CDUS Reporting SIG teleconference (John Speakman) - Work on the data parser test and provide the necessary details and updates to the SIG (Sorena Nadaf, Warren Kibbe) - Suggest agenda items for the face-to-face meeting (joint/parallel sessions, topics and time slots) - Discuss the aggregated results of CTMS/CDUS AE reporting survey when all responses are in (Joyce Niland, Rhoda Arzoomanian)